

SECTION 71. CERTIFICATE OF NEED FOR NURSING FACILITY LEVEL OF CARE PROJECTS

71.01 INTRODUCTION

These rules are promulgated pursuant to 22 M.R.S.A. §342, which authorizes the Department to adopt rules, regulations, standards, criteria, plans or procedures that may be necessary to carry out the provisions of Maine's Certificate of Need (CON) Program. These rules apply to projects involving nursing facilities, including but not limited to creation of new nursing facility services, replacement facilities, building modifications, financing, capital expenditures, changes in ownership and control, and creation of new health services by nursing facilities, as will be described more fully below. All other projects requiring CON are referred to, or may be acted upon jointly with, the Bureau of Medical Services. The purpose of the CON program is to determine whether projects falling within the scope of CON meet the statutory criteria for which a CON may be granted.

The purpose of CON is to:

- (A) Support effective health planning;
- (B) Support the provision of quality health care in a manner that ensures access to cost effective services;
- (C) Support reasonable choice in health care services while avoiding excessive duplication;
- (D) Ensure that state funds are used prudently in the provision of health care services;
- (E) Ensure public participation in the process of determining the array, distribution, quality, quantity and cost of these services;
- (F) Improve the availability of health care services throughout the State;
- (G) Support the development and availability of health care services regardless of the consumer's ability to pay; and
- (H) Seek a balance, to the extent a balance assists in achieving the purposes of this subsection, between competition and regulation in the provision of health care.
- (I) Promote the development of primary and secondary preventive health care services.

71.02 DEFINITIONS

The following words and phrases will have the following meanings:

- (A) **"Access to care"** means the ability to obtain in a timely manner needed personal health services to achieve the best possible health outcomes balanced by the health system's resource limitations. Access to care may be influenced by many factors, including, without limitation, travel, distance, waiting time, available resources, availability of a source of care and the health status of the population served.

- (B) **"Annual operating costs"** means, the total incremental costs to the facility which are directly attributable to the addition of a new health service.
- (C) **"Appropriately capitalized expenditures"** mean, those expenditures which would be capitalized if the project were implemented.
- (D) **"Bed capacity"** means, the licensed capacity of a nursing facility for each level of care it provides.
- (E) **"Bed complement"** means, licensed beds that are set up and staffed and normally available for use.
- (F) **"Capital expenditure"** means, an expenditure, including a force account expenditure or pre development activities, that under generally accepted accounting principles is not properly chargeable as an expense of operation, and, for the purpose of these rules, shall include capitalized interest on borrowed funds and the fair market value of any property or equipment which is acquired under lease or comparable arrangement or by donation.
- (G) **"Capital investment fund"** means that fund established by the Governor pursuant to Title 2, Section 101, subsection 1, paragraph D.
- (H) **"Commenced" or "commencement"** means, that:
- (1) Purchase or lease of equipment, buildings, existing facilities, or land, that the sale or lease has been consummated and the buyer or lessor is in possession and the property is being used for the purpose described in the application for which the CON was issued;
 - (2) For the new construction of a facility, part thereof, or associated structure, all pre development activity necessary to meet the remaining elements of this provision has been completed, the site has been cleared, the foundation has been fully laid and at least 50% of the approved capital expenditure has been obligated, except for projects with approved capital expenditures in excess of \$10 million where at least 50% of the portion of the total capital expenditure which was originally forecast to be completed during the 12 months following the issuance of the CON, or any extension thereto, must be obligated.
 - (3) For pre development activities, all such activities to be completed are fully obligated and such obligation requires that they be completed within the following six months;
 - (4) For modification of a health care facility not adequately covered by the above-listed requirements, all pre development activity necessary to meet the remaining elements of this provision has been completed and at least 50% of the approved capital expenditure has been obligated;
 - (5) For new health services, the service is fully operational;
 - (6) For termination of a health service, the service has been terminated and all approved capital expenditures have been obligated; or
 - (7) For changes in bed complement, the change has been completed.

- (I) **"Construction"** means, the establishment, erection, building, purchase or other acquisition of a health care facility.
- (J) **"Cost"** means, when used in conjunction with the review threshold for major medical equipment, all amounts which, under generally accepted accounting principles, are not properly chargeable as an expense of operation and maintenance and shall include the costs of installing and making the equipment operational as well as the fair market value of any equipment acquired through lease or comparable arrangement or by donation.
- (K) **"Department"** means, the Department of Human Services.
- (L) **"Development"** means, when used in connection with "health service," the undertaking of those activities that on their completion will result in the offering of a new health service to the public.
- (M) **"Expenditure minimum for annual operating costs"** for services commenced after October 1, 1998, means \$400,000 for the 3rd fiscal year, including a partial first year.
- (N) **"Generally accepted accounting principles"** means, accounting principles approved by the American Institute of Certified Public Accountants or a successor organization.
- (O) **"Health care facility"** means a hospital, psychiatric hospital, nursing facility, kidney disease treatment center, including a freestanding hemodialysis facility, rehabilitation facility, ambulatory surgical facility, independent radiological service center, independent cardiac catheterization center or cancer treatment center. The term does not include the office of a private health care practitioner, as defined in Title 24 M.R.S.A., Section 2502, subsection 1-A, whether in individual or group practice.
- (P) **"Health maintenance organizations"** Means a public or private organization that:
- (1) Provides or otherwise makes available to enrolled participants health care services, including at least the following basic health services: usual physician services, hospitalization services, laboratory services, x-ray services, emergency and preventive health services and out-of-area coverage;
 - (2) Is compensated, except for copayments, for the provision of the basic health services to enrolled participants on a predetermined periodic rate basis; and
 - (3) Provides physicians' services primarily through physicians who are either employees or partners of the organization or through arrangements with individual physicians or one or more groups of physicians.
- (Q) **"Health need"** means a situation or a condition of a person, expressed in health outcome measures such as mortality, morbidity or disability, that is considered undesirable and is likely to exist in the future.
- (R) **"Health planning"** means data assembly and analysis, goal determination and the formulation of action recommendations regarding health services.
- (S) **"Health services"** means, clinically related services, that are, diagnostic, treatment, rehabilitation services, or nursing services provided by a nursing facility. "Health services" includes alcohol abuse, drug abuse and mental health services.

- (T) **"Health services area"** means, a division or geographic area of the State of Maine, determined by the Department to have geographic logic when analyzing specific nursing facility projects.
- (U) **"Health status"** means patient or population measures, or both, of good and poor health practices, rates of death and disease, both chronic and infectious, and the prevalence of symptoms or conditions, or both, of illness and wellness.
- (V) **"Hospital"** means an institution that primarily provides to inpatients, by or under the supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment and care of injured, disabled or sick persons or rehabilitation services for the rehabilitation of injured, disabled or sick persons. "Hospital" also includes psychiatric and tuberculosis hospitals.
- (W) **"Hospital swing bed"** means, an acute care bed licensed by the Bureau of Medical Services, Division of Licensing and Certification for the use also as a nursing care bed. Swing beds may be established only in rural hospitals with fewer than 100 licensed acute care beds.
- (X) **"Major medical equipment"** means, a single unit of medical equipment or a single system of components with related functions used to provide medical and other health services and that costs \$1,200,000 or more. This term does not include medical equipment acquired by or on behalf of a clinical laboratory to provide clinical laboratory services, if the clinical laboratory is independent of a physician's office and a hospital and has been determined to meet the requirements of the U.S. Social Security Act, Title XVIII, Section 1861(s), paragraphs 10 and 11. In determining whether medical equipment costs more than \$1,200,000 the threshold provided in this subsection, the cost of studies, surveys, designs, plans, working drawings, specifications and other activities essential to acquiring the equipment must be included. If the equipment is acquired for less than fair market value, the term "cost" includes the fair market value. Beginning September 30, 2004 and annually thereafter, the threshold amount for review must be updated by the commissioner to reflect the change in the Consumer Price Index, medical index.
- (Y) **"Make available"** means with respect to a registered person directly affected by a review, one copy of the preliminary staff report shall be mailed to each such person within 5 business days of its completion
- (Z) **"Modification"** means, the alteration, improvement, expansion, extension, renovation or replacement of a health care facility, including initial equipment thereof, and the replacement of equipment or existing buildings.
- (AA) **"New Health Service" means:**
- (1) The obligation of any capital expenditures by or on behalf of a health care facility of \$110,000 or more that is associated with the addition of a health service that was not offered on a regular basis by or on behalf of the health care facility within the 12-month period prior to the time the services would be offered;

- (2) The addition of a health service that is to be offered by or on behalf of a health care facility that was not offered on a regular basis by or on behalf of the health care facility within the 12-month period prior to the time the services would be offered is projected to entail incremental annual operating costs directly attributable to the addition of that health service of at least \$400,000; or
 - (3) The addition in the private office of a health care practitioner, as defined in Title 24, section 2502, subsection 1-A, of a new technology that costs \$1,200,000 or more. The Department shall consult with the Maine Quality Forum Advisory Council established pursuant to Title 24-A, section 6952, prior to determining whether a project qualifies as a new technology in the office of a private practitioner. Beginning September 30, 2004 and annually thereafter, the threshold amount for review must be updated by the commissioner to reflect the change in the Consumer Price Index medical index. With regard to the private office of a health care practitioner, "new health service" does not include the location of a new practitioner in a geographic area. "New Health Service" does not include a health care facility that extends a current service within the defined primary service area of the health care facility by purchasing within a 12-month time period new equipment costing in the aggregate less than the threshold referred to above.
- (BB) "Nursing facility"** means a facility which is operated in connection with a hospital, or in which nursing care and medical services are prescribed by or performed under the general direction of persons licensed to practice medicine or surgery in the State, for the accommodation of convalescent or other persons who are not acutely ill and not in need of hospital care, but who do require skilled nursing care and related medical services. The term "nursing home" or "nursing facility" is restricted to those facilities, the purpose of which is to provide skilled nursing care and related medical services for a period of not less than 24 hours per day to individuals admitted because of illness, disease or physical or mental infirmity and which provides a community service. Please see 22 M.R.S.A. §1812 A and state licensing regulations.
- (CC) "Obligation"** means, a capital expenditure that is incurred by or on behalf of a health care facility, as follows:
- (1) When a contract, enforceable under Maine law, is entered into by or on behalf of the health care facility for the construction, acquisition, lease or financing of a capital asset;
 - (2) When the governing board of the health care facility takes formal action to commit its own funds for a construction project undertaken by the facility as its own contractor; or
 - (3) In the case of donated property, on the date on which the gift is completed under applicable Maine law.
- (DD) "Offer"** means, when used in connection with "health service", that the health care facility or health maintenance organization holds itself out as capable of providing or having the means to provide a health service.

- (EE) **"Person"** means, an individual, trust or estate, partnership, corporation, including associations, joint stock companies and insurance companies, the State or a political subdivision or instrumentality of the State including a municipal corporation of the State, or any other legal entity recognized by state law.
- (FF) **"Person directly affected by a review"** includes:
- (1) the applicant;
 - (2) A group of 10 persons residing or located within the health service area served or to be served by the applicant;
 - (3) A health care facility, a health maintenance organization or a health care practitioner that demonstrates that it provides similar services or, by timely filing a letter of intent with the Department for inclusion in the record, indicates an intention to provide similar services in the future to patients residing in the health service area and whose services would be directly and substantially affected by the application under review;
 - (4) A 3rd-party payor, including, without limitation, a health maintenance organization, that pays health care facilities for services in the health service area in which the project is proposed to be located and whose payments would be directly and substantially affected by the application under review; and
 - (5) A person who demonstrates a direct and substantial effect upon that person's health care as a result of the application under review..
- (GG) **"Pre development activity"** means, any appropriately capitalized expenditure by or on behalf of a health care facility made in preparation for the offering or development of a new health service for which a CON would be required and arrangements or commitments made for financing the offering or development of the new health service; and shall include site acquisitions, surveys, studies, expenditures for architectural designs, plans, working drawings and specifications.
- (HH) **"Project"** means, any acquisition, capital expenditure, new health service or change in a health service, pre development activity or other activity that requires a CON under Title 22 M.R.S.A., Section 329.
- (II) **"Regular basis"** means, when used in conjunction with the definition of a new health service offered on a routine basis in such a manner as to reasonably accommodate the diagnostic, treatment or rehabilitation needs of persons on at least a weekly basis and provided on at least 50% of the normal business days during which the service is offered within the 12-month period prior to the time the service is intended to be offered.
- (JJ) **"Rehabilitation facility"** means an inpatient facility that is operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of medical services and other services that are provided under competent professional supervision.

- (KK) **"Replacement equipment"** means a piece of capital equipment that replaces another piece of capital equipment that performs essentially the same functions as the replaced equipment.
- (LL) **"Significant change in financing"** means, changes in the principal amount, interest rate and term of debt financing, the nature of the payback provisions on debt financing (e.g. level-debt schedule or level-principal schedule), the amount and nature of equity contributions, the annual amount and duration of depreciation expense changes.
- (MM) **"State Health Plan"** means the plan developed in accordance with Title 2 M.R.S.A., Chapter 5.

71.03 SCOPE OF CON-COVERED ACTIVITIES

- (A) **Certificate of Need Required.** A person may not enter into any commitment for financing a project that requires a CON or incur an expenditure for the project without having sought and received a CON. This prohibition does not apply to obligations for financing conditioned upon the receipt of a CON or to obligations for pre development activities. Except as provided in the CON Act and these rules, a CON is required for:
- (1) **Transfer of ownership, acquisition by lease, donation, transfer; acquisition of control.** Any transfer of ownership or acquisition of a nursing facility under lease, or comparable arrangement or through donation or any acquisition of control of a health care facility under lease, management agreement or comparable arrangement or through donation that would have required review if the transfer or acquisition had been by purchase, except in emergencies when that acquisition of control is at the direction of the Department. The commissioner shall issue a CON for a project that involves the acquisition of control of a health care facility when the acquisition consists of a management agreement or similar arrangement and primarily involves the day-to-day operation of the facility in its current form if the commissioner determines that: (1) the project meets the requirements of section 71.05 (L) (5), and; (2) that the project is economically feasible in light of its impact on the operating budget of the facility and the applicant and the applicant's ability to operate the facility without increases in the facility's rates beyond those that would otherwise occur absent the acquisition;
 - (2) **Acquisitions of certain major medical equipment.** Acquisitions by or on behalf of a nursing facility of major medical equipment with a cost of \$1,200,000 or more. The use of major medical equipment on a temporary basis in the case of a natural disaster, major accident or equipment failure and the use of replacement equipment does not require a CON;
 - (3) **Capital expenditures.** The obligation by a nursing facility, when related to nursing services provided by the nursing facility, of any capital expenditure of \$510,000, or more Every 2 years, beginning January 1, 2005, the Department shall review the monetary limit and revise the limit to correspond to changes in the Consumer Price Index medical index by adopting rules setting the new figures. A CON is not required for a nursing facility to convert beds used for the provision of

nursing services to beds to be used for the provision of residential care services. If such a conversion occurs, public funds are not obligated for payment of services provided in the converted beds;

- (4) **New health service.** The offering or development of any new health service. For purposes of this section, “new health service” includes only the following:
- (a) The obligation of any capital expenditures by or on behalf of a health care facility of \$110,000 or more that is associated with the addition of a health service that was not offered on a regular basis by or on behalf of the health care facility within the 12-month period prior to the time the services would be offered; or
 - (b) The addition of a health service that is to be offered by or on behalf of a health care facility that was not offered on a regular basis by or on behalf of the health care facility within the 12-month period prior to the time the services would be offered and that, for the 3rd fiscal year of operation, including a partial first year, following addition of that service, is projected to entail incremental annual operating costs directly attributable to the addition of a new health service of at least \$400,000.
- A CON is not required for a health care facility that extends a current service within the defined primary service area of the health care facility by purchasing within a 12-month time period new equipment costing in the aggregate less than \$1,200,000.
- (5) **Other.**
- (a) Any increase in the licensed bed complement of a nursing facility;
 - (b) Any increase in the licensed bed complement or bed capacity of a hospital that includes swing beds or licensed nursing beds;
 - (c) The construction, development or other establishment of a new or replacement nursing facility or the addition by a hospital of nursing facility services;
 - (d) Acquisitions and transfers.
 - (e) A new health service not otherwise subject to review under these rules and not reviewed and approved prior to commencement of new services will require a CON if its actual 3rd fiscal year operating costs exceed \$400,000.
 - (f) Any projects that the Department determines are related projects if such projects, considered in the aggregate, would otherwise require a CON under this section.

- (B) **Exemptions.** Except as otherwise specifically provided, nothing in these rules shall be construed to preempt, replace or otherwise negate the requirements of any other laws or regulations governing health care facilities. The requirements of this Act shall not apply with respect to:

- (1) A health care facility operated by religious groups relying solely on spiritual means through prayer for healing;
 - (2) Activities or acquisitions by or on behalf of a health maintenance organization or a health care facility controlled, directly or indirectly, by a health maintenance organization or combination of health maintenance organizations to the extent mandated by the National Health Policy, Planning and Resources Development Act of 1974, as amended and its accompanying regulations;
 - (3) Expenditures undertaken in one accounting period that involve exclusive replacement of equipment and includes no other expense that in combination with replacement of equipment, would exceed the threshold.
 - (4) Conversion of licensed nursing home beds used for the provision of nursing services to beds licensed for the provision of residential care services,
 - (5) Assisted living programs and services regulated under chapter 1665.
 - (6) Conversion of a critical access hospital of acute care beds to hospital swing beds.
 - (7) Hospice services and Home Health Care services offered by a home health care provider.
- (C) **Divisions prohibited.** No person shall separate portions of a single project into components, including, but not limited to, site, facility and equipment, to evade the cost limitations or other requirements of these rules.
- (D) **Time spans specified.**
- (1) No person required to obtain a CON shall split what should properly be considered a single capital expenditure into discrete components undertaken during more than one accounting period (generally one fiscal year) to evade the cost thresholds of the program. In determining whether a particular project involves a capital expenditure requiring a CON, the Department will take into consideration the aggregate cost of any future components of such project that are proposed to be undertaken during a thirty-six (36) month period beginning on the date the obligation for the first such component is incurred.
 - (2) In determining whether a proposal involves licensed bed capacity changes requiring a CON, the Department will take into separate consideration increases, decreases, redistribution and relocations occurring over two-year periods subsequent to the effective date of the program.
- (E) **Subsequent Review.** After a CON has been issued, changes occurring in an approved project may require subsequent review. A subsequent review is required if any of the following changes occur within three years after the approved activity is commenced:
- (1) There is a significant change in operating or capital financing;
 - (2) There is a change affecting the licensed or certified bed capacity as approved in the CON (except if nursing facility beds are converted to residential care beds);

- (3) There is a change involving the addition or termination of the health services proposed to be rendered by the health care facility;
- (4) There is a change in the site or the location of the proposed health care facility; or
- (5) There is a substantial change proposed in the design of the health care facility or the type of construction.

(F) Procedures for subsequent review.

- (1) The holder of an approved CON is responsible for notifying the Department in writing within 30 days of determining that circumstances exist that require subsequent review. The written notice shall set forth the following information:
 - (a) The nature of the proposed change;
 - (b) The need for the change including, where appropriate, an explanation of why the change was not set forth in the original application or letter of intent; and
 - (c) Other pertinent details subject to the procedures and criteria set forth in these rules.
- (2) Within 30 days of receipt of this written notice, the Department shall:
 - (a) advise the holder of an approved CON in writing whether the proposed change is approved, or
 - (b) if not approved, the application must be treated as a new application under the CON Act..
 - (c) If approved, the department shall amend the CON as appropriate.
- (3) Any proposal for subsequent review that would be reviewable under applicable sections of these rules if it were not an amendment to an existing CON, may be given a full review in accordance with applicable review procedures.

- (G)** Review following approval. When the commissioner approves an application unconditionally or subject to conditions pursuant to the CON Act, the commissioner may conduct a review to ensure compliance with any terms or conditions of the approval within 3 years after the approved activity is undertaken. In this review, the commissioner may hold a public hearing and may consider any significant changes in factors or circumstances relied upon by the commissioner in approving the application and significant and relevant information that either is new or was withheld by the applicant at the time of the process under the CON Act. If, upon review, the commissioner determines that any terms or conditions of the approval have not been met, the commissioner may take enforcement action consistent with the CON Act.

71.04 IMPLICATIONS OF NONCOMPLIANCE.

(A) **Withholding of licenses.** No new health care facility, as defined above, shall be eligible to obtain a license under applicable state law, if the project has not obtained a CON as required by the CON Act. The license of any facility shall not extend to include or otherwise be deemed to allow the delivery of any services, the use of any equipment which has been acquired, the use of any portion of a facility or any other change for which a CON is required if such has not been obtained. Any unauthorized delivery of services, use of equipment or portion of a facility, or other change shall be deemed to be in violation of the respective chapter under which the facility is licensed.

(B) **Withholding of reimbursement.**

(1) No health care facility or other provider may be eligible to apply for or receive any reimbursement, payment or other financial assistance from any state agency or other third party payer, either directly or indirectly, for any capital expenditure or operating costs attributable to any project for which a CON was required by the CON Act but has not been obtained. For the purposes of this section, the Department shall determine the eligibility of a facility to receive reimbursement for all projects subject to the provisions of the CON Act.

(2) Facilities and persons subject to the provisions of the CON Act shall only be eligible to receive State funds for periods commencing after the Department's final decision with regard to the CON. Consequently, failure to give timely notice of intent to initiate a project subject to review shall result in the denial of State reimbursement, payment or financial assistance for all costs related to the project for the period of time preceding the Department's decision, even if the Department ultimately decides to issue a CON for the project. The denial of such State reimbursement shall not be imposed where the Department has previously made a written determination, based upon proper disclosure of all relevant fact, that the project is not subject to review in accordance with CON law and rules, even if the Department should find it necessary to reverse that determination based on new, different or supplemental information. The amount of reimbursement or payment to be denied by State agencies for failure to give timely notice will be as follows:

- (a) for projects which do not involve a capital expenditure, all operating costs related to the project, for the period of time preceding the Department's decision to grant a CON; or
- (b) for projects which involve a capital expenditure:
 - * all operating costs related to the project for the period of time preceding the Department's decision to grant a CON; and
 - * the portion of total capital costs (including depreciation, amortization, interest, and return on owner's equity) related to the project, which is represented by a fraction, the numerator of which is the amount of the total capital expenditure obligated prior to the Department's decision to

grant a CON and the denominator of which is the total capital expenditure related to the project, for all accounting periods before and after the Department's decision.

- (C) **Injunction.** The Department may seek to enjoin any project for which a CON is required but not obtained, and may take any other action as may be appropriate to enforce the CON Act and these rules.
- (D) **Penalty.** Whoever violates any provision of the CON Act, or any rate, rule or regulation established pursuant to the CON Act shall be subject to a civil penalty payable to the Treasurer, State of Maine, of not more than \$5,000 to be recovered in a civil action.

71.05 APPLICATION PROCESS

(A) Letter of Intent.

- (1) Prior to filing an application for a CON, an applicant shall file a **Letter of Intent (LOI)** with the Department. The LOI shall form the basis for determining whether the proposed expenditure or action is subject to CON review. It will expire in 12 months of receipt unless an application is received by the Department within that time period. The applicant is not precluded from resubmitting the same letter of intent.
- (2) **The LOI must contain** the following information in sufficient detail to allow the Department to determine whether the expenditure or action is subject to review:
 - (a) A request for a ruling regarding the applicability of CON to the proposal;
 - (b) A brief description, including location, of the proposed project. The project should, to the extent practicable, be described in terms which permit comparison to the scope of CON contained in Section 71.03;
 - (c) An estimate of any capital expenditure or annual operating cost of the proposed project, and anticipated utilization;
 - (d) Anticipated date on which management services will commence, or an obligation for any proposed capital expenditure is to be incurred, nature of obligation and amount;
 - (e) Anticipated date of submission of an application if one is required;
 - (f) Anticipated date of commencement of the proposed project (e.g. initiation of construction, acquisition of equipment); and
 - (g) Anticipated date of completion of the proposed project or date on which services will first be offered to the public.
- (3) **Response by Department**
 - (a) After receiving the letter of intent, the Department shall notify the applicant whether the proposed project is subject to review or advise that additional information is needed before making a determination. If the Department determines that the proposed project is subject to review, the

Department shall issue a letter or checklist, or both, to an applicant that stipulates and clarifies what will be required in the application.

- (b) Within 30 days of filing the letter of intent, the applicant shall meet with the Department staff in order to assist the Department in understanding the application and to receive technical assistance concerning the nature, extent and format of the documentary evidence, statistical data and financial data required for the Department to evaluate the proposal. The Department may not accept an application for review until the applicant has satisfied this technical assistance requirement.
- (c) After receiving notice from the Department that a CON is required for a proposed expenditure or action, if the applicant wishes to proceed with the project, the applicant must file an application for a certificate of need.
- (4) **Non-applicability determination.** A determination by the Department that a CON is not needed for a proposal is considered a "non-applicability determination" and permits the person to proceed with the proposed project without risk of having sanctions or other penalties imposed. However, if the Department receives new information indicating that a non-applicability determination was based on partial or inaccurate facts, the determination may be rescinded and a new applicability determination will be made.

(B) Filing of an Application.

- (1) A non-refundable filing fee must be paid at the time the application is filed. Fees are determined as follows:
 - (a) Fees shall be computed at \$1,000 per \$1,000,000, or part thereof, of the proposed capital expenditure or third year operating costs, whichever is higher.
 - (b) The minimum fee is \$1,000.
 - (c) If the approved capital expenditure or operating costs on which the fees were based are higher than the initially proposed capital expenditure, the difference in fees, if any, must be paid before the CON can be issued.
 - (d) Applications for which review is suspended for more than six months shall be assessed a filing fee equal to that of a new application when review is reactivated.
- (2) The application must describe with specificity how the proposed project meets each of the conditions for granting a certificate of need required by this chapter. A statement or statements that the project will meet the conditions without supporting facts backed by relevant documentation and analysis constitute sufficient cause to deny the application. Information may include, but is not limited to the disclosure of identities of interested and related parties, a list of facilities in which the applicant, either directly or indirectly, has ownership or management interests, statements of deficiencies and plans of correction from licensing/certification activities, financial statements and financial projections,

etc. An application subject to full review must contain, if available and relevant to the particular service or technology, information on health status, characteristics of the payor mix for the population to be served, public health need for the service or technology, quality assurance processes and prevention programs.

- (3) The application shall be in the format specified in the Department's Comprehensive Application Format, unless an alternative format is agreed to at the technical assistance meeting.
- (4) The applicant shall provide two copies of a summary of all actions taken by the Department to enforce regulations or improve quality of care, including the implementation or completion of adverse actions according to the Federal State Operations Manual necessary to enforce Conditions/Standards of Participation, and all civil or criminal actions (identifying where possible the name, court, docket number, and outcome for each case) pending or decided against any such facility or service within the most recent three-year period.
- (5) An application is certified as complete when the applicant delivers to the Department a certification in writing that states that the application should be considered complete by the Department. Subsequent to the applicant's certification under this subsection, the applicant may submit information that is responsive to any concern, issue, question or allegation of facts contrary to those in the application made by the Department or another person.
- (6) Within 5 business days of the filing of a certificate by an applicant that a complete certificate of need application is on file with the Department, the applicant shall publish, at its' expense, a public notice prepared by the Department, that the application has been filed and that a public informational meeting must be held regarding the application. Such notice must be given by publication in a newspaper of general circulation in Kennebec County and in a newspaper published within the service area in which the proposed expenditure will occur. This notice must also be provided to all persons who have requested notification by means of asking that their names be placed on a mailing list maintained by the Department for this purpose. This notice must include:
 - (a) A brief description of the proposed expenditure or other action;
 - (b) A description of the review process and schedule;
 - (c) A statement that any person may examine the application, submit comments in writing to the Department regarding the application and examine the entire record assembled by the Department at any time from the date of publication of the notice until the application process is closed for comment; and
 - (d) The time and location of the public informational meeting and a statement that any person may appear at the meeting to question the applicant regarding the project or the Department regarding the conditions that the applicant must satisfy in order to receive a CON for the project.

The Department shall make an electronic or stenographic record of the public informational meeting.

- (7) During the review period, prior to the date that Department staff submits a final report to the commissioner, an applicant may withdraw an application without prejudice by filing written notice of the withdrawal with the Department. A withdrawn application may be resubmitted and will be processed as an entirely new application under this chapter.
- (C) **Competitive reviews.** In cases of competitive reviews, applicants shall submit additional information within 30 business days or within a longer period of time, provided that the Department and all competing applicants agree.
- (D) **Automatic withdrawal.** Any incomplete application is considered withdrawn if the applicant fails to respond to a request for additional required information within 180 days of the date the request was forwarded by the Department.
- (E) Consultation on new technologies and needs. In connection with the development of policies and procedures to implement this Act, the commissioner may, from time to time, consult with persons with relevant skills and experience regarding new medical technologies and the impact of those technologies on the health care delivery system in the State; and the unmet need for health care services in the State.
- (F) **Review Process.** The review process consists of an evaluation of the project application for a CON by the Department in light of the application itself, material collected or developed by or for the Department staff to test the assertions in the application, all comments received by any person regarding the project and any other material made part of the record.
- (G) **Public Hearings.** The following provisions apply to a public hearing under this chapter:
 - (1) The commissioner or the commissioner's designee may hold a public hearing regarding the application.
 - (2) The commissioner, or the commissioner's designee, shall hold a public hearing if 5 persons residing located within the health service area to be served by the applicant request, in writing, that such a public hearing be held and the request is received by the commissioner no later than 30 days following the informational hearing on the application conducted pursuant to section 71.05 (B) (6). The public hearing shall be noticed publicly and held within 20 business days of the receipt of the request, unless a longer timeframe is agreed to by the applicant, the persons requesting the public hearing and the Department.
 - (3) The public hearing shall be conducted in a geographic location reasonably close to the location of the intended project. The public hearing will be an opportunity for the Department, any person directly affected by a review and the public to receive information relative to the application. The applicant, any other person directly affected by a review and the public will be permitted to introduce verbal or written testimony and/or evidence. Witnesses will not be sworn. The

commissioner's designee may, at its sole discretion, prepare an agenda for a public hearing that includes reasonable limits on the amount of time allotted for the presentation of verbal testimony and/or evidence.

- (4) An electronic or stenographic record of the public hearing must be made part of the record.
 - (5) The Department will accept written comments regarding the application for 10 days after the close of the public hearing.
- (H) **Preliminary staff analyses.** As soon as practicable, the Department staff shall provide the preliminary analyses of the application and the record to the applicant, the commissioner and any person who requests the analyses and record. Notice of the availability of the analyses must be published in a newspaper in general circulation serving the area in which the project is to be located and on the department's publicly accessible site on the Internet. Such notice will be at the applicant's expense. Ten days after the notice is published in the newspaper the public record will be closed.
- (I) Final department staff analysis. A final Department staff analysis must be submitted to the commissioner, together with the documentary record described in section 71.05 (H) (5), as soon as practicable after the closing of the record.
- (J) Reviews. To the extent practicable, a review must be completed and the commissioner shall make a decision within 90 days after the application has been certified as complete by the applicant. The Department shall determine when it is not practicable to complete a review within 90 days according to the criteria described in section 71.05 (L). Whenever it is not practicable to complete a review within 90 days, the Department may extend the review period for up to an additional 60 days.
- (K) **Public necessity.** The Department may delay action on an otherwise complete application for up to 180 days from the time the application has been certified as complete by the applicant if the Department finds that a public necessity exists. The Department shall provide written notice of the delay to the applicant and any other person who has requested in writing information regarding the application. For purposes of this subsection, the Department shall find that a public necessity exists if:
 - (1) The application represents a new service or technology not previously provided within the State.
 - (2) The application represents a potential significant impact on health care system costs.
 - (3) The application represents a new service or technology for which a health care system need has not been previously established.
 - (4) There are several applications for the same or similar projects before the Department.

(L) Types of Review

- (1)** The Department may conduct any of the following types of reviews:
 - (a)** A simplified review.
 - (b)** A full review.
 - (c)** An extended review.
- (2)** A simplified review will be accorded those projects which:
 - (a)** Meet an already demonstrated need as established by applicable state health plans or as determined by rules of the Department; or
 - (b)** Are required solely to meet federal, state or local life safety codes if the project involves a health facility, major medical equipment or a new health service that has previously received a CON.
 - (c)** The Department shall waive the requirements of an extended review or a full review and conduct a simplified review process in accordance with this section for an acquisition of control of health care facilities pursuant to Section 71.03(A)(1) if the acquisition consists of a management agreement or similar arrangement and primarily involves the day-to-day operation of the facility in its current form.
 - (d)** The project primarily involves the maintenance of a health facility if the commissioner determines that the project will result in no or a minimal additional expense to the public or to the health care facility's clients; will be in compliance with other applicable state and local laws and regulations; and will significantly improve or, in the alternative, not significantly adversely affect the health and welfare of any person currently being served by the health care facility.
 - (e)** The capital expenditure is required to eliminate or prevent imminent safety hazards, as defined by applicable fire, building or life safety codes and regulations; to comply with state licensure standards; or to comply with accreditation or certification standards that must be met to receive reimbursements under the United States Social Security Act, Title XVIII or payments under a state plan for medical assistance approved under Title XIX of that Act.
 - (f)** The economic feasibility of the project is demonstrated in terms of its effects on the operating budget of the applicant, including its existing rate structure.
 - (g)** There remains a public need for the service to be provided.
 - (h)** The corrective action proposed by the applicant is the most cost effective alternative available under the circumstances.
 - (i)** Are determined by the Department to warrant such a review.

- (3) An extended review will be utilized whenever it is not practicable to complete a review within 90 days. Whenever possible, the decision to utilize an extended review period will be made when the application is declared complete. The following are types of projects for which it is not practicable to complete a review within 90 days:
- (a) Construction projects involving capital expenditures in excess of five million dollars;
 - (b) Proposed new health services not previously offered or issued CON's in the State;
 - (c) Competing applications; or
 - (d) Proposals involving the construction, addition or replacement of more than 120 nursing facility beds.
- (4) The Department will accept no application for any type of new nursing facility beds unless there has been a specific appropriation for new beds from the legislature. In the event of such an appropriation, this section establishes the procedures for review of applications. To the extent that a procedure is not fully covered by this section, reference is made to other applicable provisions of these rules.
- (a) Priority areas. The Department will provide data on the need for new nursing facility beds in each health service area. Beds will be allocated to one or more of these priority areas. The Department will publish a notice in the Kennebec Journal and a newspaper in general circulation in the health service areas of highest priority. The notice will announce that the Department is requesting competing proposals, and establish dates by which letters of intent applications must be received by the Department.
 - (b) Review of applications. Reviews will be conducted consistent with established procedures governing review of competing applications or non-competing applications, as appropriate.
 - (c) This section does not apply to applications for transfer of ownership of existing nursing facilities, renovation and/or modification of existing nursing facilities without adding new beds, or replacement of existing (currently licensed and operating) deficient nursing facility beds.
 - (d) Nursing facility projects that propose to add new nursing facility beds to the inventory of nursing facility beds within the State may be grouped for competitive review purposes consistent with appropriations made available for that purpose by the Legislature.
- (5) **Replacement beds/facility.** Nursing facility beds that are not in service (not currently licensed) cannot be replaced without a new appropriation unless a purchase and sale agreement transferring rights to replace the beds was entered into prior to the expiration of the license.

- (6) **Bed banking.** A nursing facility that voluntarily reduces the number of licensed beds may convert the beds back (relicense the beds) and increase the number of nursing facility beds to no more than the previously licensed number of nursing facility beds pursuant to this subsection if the following conditions are met:
- (a) The reduction in licensed beds did not create additional private rooms in the facility;
 - (b) The facility has been in continuous operation;
 - (c) The facility has not been purchased or leased;
 - (d) The facility provided notice of its intent to preserve conversion options to the Department no later than 30 days after the effective date of license reduction;
 - (e) The application is received by the Department within four (4) years of the effective date of the license reduction or within eight (8) years if the Department has provided a one-time four (4) year extension for good cause; and
 - (f) The facility has obtained a CON. If no new construction is required for the conversion of banked beds, the application will be given an expedited review pursuant to Section 71.05(L)(8).
 - (g) The annual total of reopened beds approved by the Department does not exceed 100.
- (7) **Effect of banked beds on other review proceedings.** Nursing facility beds that have been banked under Section 71.05(L)(6) are considered as available nursing facility beds for purposes of evaluating need under Section 71.05(N) so long as the facility retains the ability to convert them back to nursing facility use, unless the facility indicates, in response to an inquiry from the Department in connection with an ongoing project review, that it is unwilling to convert them to meet a need identified in that project review.
- (8) **Expedited review.** A request to convert banked beds where no construction is required to do so will be provided an expedited review. The scope of review under this section will consist of the following:
- (a) Review of the historical costs of operating the beds to determine whether the projected costs are consistent with the cost of operating the beds prior to closure, adjusted for inflation and case mix;
 - (b) The application must meet the requirements of Section 71.05(N)(1) except that subsection (b) of that section shall be based on (a), above.
- (9) **Extensions of review period.** Any review period may be extended with the written consent of the applicant. The request to extend the review period may be initiated by the applicant or the Department. If the request is initiated by the Department, it shall not be effective unless consented to by the applicant in

writing. If the applicant initiates the request, the Department shall agree to the requested extension if it determines that the request is for good cause.

- (10) **Mailing list of persons who have requested notification of the beginning of a review.** The Department shall provide notice to all persons who have requested notification by means of asking that their names be placed on a mailing list maintained by the Department for this purpose. The Department will provide notice of the beginning of a review for all types of projects for which notification is requested.
- (M) **Approval; Record.** This section applies to determinations by the commissioner under this chapter.
- (1) **Basis for decision.** Based solely on a review of the record maintained under 71.05 (M)(6), the commissioner shall approve an application for a CON if the commissioner determines that the project meets the conditions set forth in section N.
- (2) **Communications.** Except as otherwise provided in the CON Act, only a person who is a full-time employee of the department with responsibilities for the CON program, a consultant to the project or a policy expert pursuant to section 71.05(E) may communicate with the commissioner regarding any application for a CON or any letter of intent. Nothing in this section limits the authority or obligation of the staff of the Department with responsibility for the certificate of need program to meet with, or otherwise communicate with, any person who is not a Department employee and who wants to provide information to be considered in connection with an application for a CON.
- (3) **Limited communications.** A person who is not a Department employee may not communicate with any Department staff regarding the merits of a certificate of need application except for the purpose of placing that person's views in the application record. All communications with Department staff responsible for the certificate of need program from any person who is not a Department employee that the Department staff reasonably believes is intended to influence the analyses relating to or the decision regarding any application for CON must be noted by that Department staff and that notation must be made part of the application record.
- (4) **Decision.** The commissioner's decision must be in writing and must contain appropriate references to the record. If the application is denied, the decision must specifically address comments received and made part of the record that favor granting the application. If the application is approved, the decision must specifically address comments received and made part of the record that favor denial of the application.
- (5) **Record.** The record created by the Department in the course of its review of an application must contain: a) The application and all other materials submitted by

the applicant for the purpose of being made part of the record. b) All information generated by or for the Department in the course of gathering material to assist the commissioner in determining whether the conditions for granting an application for a CON have or have not been met. This information may include, without limitation, the report of consultants, memoranda of meeting or conversations with any persons interested in commenting on the applications, letters, memoranda and documents from other interested agencies of State Government and memoranda describing officially noticed facts. c) Stenographic or electronic recordings of any public hearing held by the commissioner or the staff of the Department at the direction of the commissioner regarding the application. d) Stenographic or electronic recording of any public informational meeting held by the Department. e) Any documents submitted by any person for the purpose of being made part of the record regarding any application for a CON or for the purpose of influencing the outcome of any analyses or decisions regarding an application for CON, except documents that have been submitted anonymously. Such source-identified documents automatically become part of the record upon receipt by the department and f) Preliminary and final analyses of the record prepared by the staff and g) Written assessments by the Director of the Bureau of Health and the Superintendent of Insurance assessing the impact of the application on the health care system or cost of health insurance in the State.

- (6) **Maintenance of the record.** The record created pursuant to Section 71.05 (M)(5) first opens on the day the Department publishes its notice that an application for a CON has been filed. From that day, all of the record is a public record, and any person may examine that record and purchase copies of any or all of that record during the normal business hours of the Department. The record is closed 10 days after a public notice of the closing of the record has been published in a newspaper of general circulation in Kennebec County, in a newspaper published within the service area of the project and on the department's publicly accessible site on the Internet, as long as the notice is not published until after the preliminary staff analysis of the application is made part of the record.

(N) **Principles Governing Review.**

- (1) **Determinations required.** A CON shall be issued whenever the commissioner determines and makes specific written findings regarding that determination that:
- (a) The applicant is fit, willing and able to provide services at the proper standard of care as demonstrated by, among other factors, whether the quality of any health care provided in the past by the applicant or a related party under the applicant's control meets industry standards;
 - (b) The economic feasibility of the proposed services is demonstrated in terms of the capacity of the applicant to support the project financially over its useful life, in light of the rates the applicant expect to be able to charge for the services to be provided by the project; and the applicants ability to

establish and operate the project in accordance with existing and reasonably anticipated future changes in federal, state and local licensure and other applicable or potentially applicable rules;

- (c) There is a public need for the proposed services as demonstrated by the extent to which the project will substantially address specific health problems as measured by health needs in the area to be served by the project, whether the project will have a positive impact on the health status indicators of the population to be served, whether the services affected by the project will be accessible to all residents of the area proposed to be served, and whether the project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project.
 - (d) The proposed services are consistent with the orderly and economic development of health facilities and health resources for the state in accordance with the State Health Plan, that the impact of the project on total health care expenditures after taking into account, to the extent practical, both the cost and benefits of the project and the competing demands in the local service area and statewide for available resources for health care, that state funds are available to cover any increase in state costs associated with the utilization of the project's services and the likelihood that more effective, more accessible or less costly alternative technologies or methods of service delivery may become available. In making a determination under this subsection, the commissioner shall use data available in the state health plan under Title 2, M.R.S.A., section 103, data from the Maine Health Data Organization established in Title 22 M.R.S.A., chapter 1683 and other information available to the commissioner. Particular weight must be given to information that indicates that the proposed health services are innovations in high quality health care delivery, that the proposed health services are not reasonably available in the proposed area and that the facility proposing the new health services is designed to provide excellent quality health care.
 - (e) The project is consistent with the State Health Plan.
 - (f) The project ensures high-quality outcomes and does not negatively affect the quality of care delivered by existing service providers.
 - (g) The project does not result in inappropriate increases in service utilization according to the principles of evidence-based medicine adopted by the Maine quality Forum, as established in Title 24-A M.R.S.A., section 6951.
- (2) **Conditional approvals.** The commissioner may grant an application subject to conditions that relate to the criteria for approval of the application.
- (3) **Criteria.** In determining whether to issue or deny a CON, the Department shall, among other criteria, consider the following:

- (a) Whether the project will substantially address specific problems or unmet needs in the area to be served by the project;
- (b) Whether the project will have a positive impact on the health status indicators of the population to be served;
- (c) Whether the services affected by the project will be accessible to all residents of the area proposed to be served. Accessibility is determined through analysis of the area including population, topography and availability of transportation and health services;
- (d) Whether there are less costly or more effective alternate methods of reasonably meeting identified health service needs of the project;
- (e) Whether the project is financially feasible in both an intermediate and long-term time frame;
- (f) Whether the project would produce a cost benefit in the existing health care system of the State and the area in which the project is proposed;
- (g) Whether the quality of any health care provided by the applicant in the past meets industry standards;
- (h) Whether the project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project;
- (i) The immediate and long-term financial and economic feasibility of the proposal, as well as the probable effect of the proposal on the costs of and charges and net patient revenues for providing health services by the person proposing the project;
- (j) The effect of the means proposed for the delivery of health services on the clinical needs of health professional training programs in the area in which the services are to be provided and, if applicable, the extent to which the health profession schools, if any, in the area will have access to the services for training purposes;
- (k) The probable impact of the proposal being reviewed on the costs of providing health services by the person proposing the construction project and on the costs and charges to the public of providing health services by other persons;
- (l) The special circumstances of health care facilities with respect to conserving energy;
- (m) The effect of competition on the supply of the health service being reviewed and the system wide cost of health care; provided, however, that this provision shall not be interpreted to mean that the Department is obligated to approve a project to increase competition where such increased competition is likely to increase system-wide health care costs;

- (n) In the case of health services or facilities proposed to be provided, the efficiency, appropriateness and cost-effectiveness of the use of existing services and facilities similar to those proposed;
 - (o) In the case of health services or facilities, the quality of care provided by those facilities in the past.
 - (p) Any information submitted by the applicant or developed by the Department as well as any other pertinent information concerning the fitness, willingness, or ability of the applicant to provide the proposed services at the proper standard of care.
- (4) **Standards applied in CON.** In addition to the criteria in (3) above, standards applicable to projects reviewed by the Department may include but are not limited to:
 - (a) Functional area space requirements. Gross square footage shall not exceed 500 per licensed NF bed without justification of need.
 - (b) Land and land improvements. Only the minimum amount of land necessary to satisfy local requirements, if applicable, or to situate the building and provide adequate parking will be allowed. The applicant shall provide comparative cost information to support the cost of land and land improvements to determine whether the cost is reasonable and necessary.
 - (c) Fees for architectural and engineering services. Any design fees that exceed the State of Maine Recommended Fee Schedule for Design of Public Improvements (current edition) shall be accompanied by justification by the applicant and determined necessary by the Department in order to be approved.
 - (d) Contingency fees. Contingency fees shall not exceed 5% of the construction budget. Each approved CON is automatically granted 5% leeway on the total construction cost up to a maximum of \$200,000. Therefore, the contingency fee included as part of the approved construction budget shall be kept to a minimum.
 - (e) Developer fees. Developer fees will not be allowed. Applicants must detail actual costs of the applicant for the design and implementation of the construction project.
 - (f) Moveable equipment. Moveable equipment, excluding computers, printers and networking, shall not exceed \$5,000/bed.
 - (g) Computer systems. The applicant shall provide a detailed description of the computer system to be installed and its functionality. Functionality must justify the cost, and the applicant shall provide comparative bidding information for technology services.
 - (h) Construction cost per square foot. The calculation of construction costs shall include land and land development costs, architect/engineering fees,

construction supervision, construction, other design/consultant costs related to construction, insurance during construction, municipal permits and interest during construction. Construction costs per square foot shall be compared against Marshall and Swift Valuation Services (calculator and segregated cost methods) to determine reasonableness.

- (i) Bed need. Statistical bed need will be based upon no more than 110 beds/1,000 persons over the age of 75 in the most current census. The Department will utilize the Maine Hospital Analysis Areas contained in Maine Health 1998, or as amended, to determine geographic need.
- (j) Nursing hours. Nursing hours shall be comparable to the hours for similar facilities with respect to size and case mix. The department will utilize the most current audited data for the year in which over 50% of the nursing homes have audits on file. This data is available upon request through the Department's Bureau of Medical Services.

(O) Scope of Certificates Issued.

- (1) **Application determinative.** A CON shall be valid only for the defined scope; premises and facility or person named in the application and shall not be transferable or assignable.
- (2) **Maximum expenditure.** In issuing a CON, the Department shall specify the maximum capital expenditures, which may be obligated under the certificate. The maximum capital expenditure for any project involving a capital expenditure shall be (1) the amount approved by the Department plus (2) 5% of the approved amount, not to exceed a maximum of \$200,000.
- (3) **Procedure for monitoring capital expenditures.** Each holder of a CON is required to make a written report at the end of each 6-month period following its issuance regarding implementation activities, obligations incurred, expenditures made and other matters, pursuant to Section 71.05(R).
- (4) **Excess capital expenditures.** In the event the Department determines that the holder of a CON has exceeded the prescribed capital expenditure maximum or is expected to do so, it shall notify the holder. The following procedures will be followed:
 - (a) If the holder confirms that it either has or is likely to exceed the capital expenditure maximum, it shall submit a written report detailing the amount of and reason for the cost overrun and such other information as the Department may prescribe, within ten (10) days of receipt of notice. If the holder denies that the capital expenditure maximum is likely to be exceeded, the Department may, at its discretion, conduct an audit of the holder's records. If an audit conducted by or on behalf of the Department reveals that the holder either has or is likely to exceed the capital expenditure maximum, the holder shall provide written explanation of the overrun within ten (10) days of receipt of written notice. Nothing in this

section will prohibit any holder of a CON from voluntarily disclosing that it either has or is likely to exceed the maximum capital expenditure as soon as practicable after it becomes known. The holder shall explain in writing the amount of and reason for the cost overrun and such other information as the Department may prescribe.

- (b) Once the Department receives written confirmation and explanation of the cost overrun, the Department shall, within 30 days of receipt of the report and related information, make a written determination of whether the additional costs are approved. In making this determination, the Department will determine, among other factors, that the project remains economically feasible and that the additional cost is necessary and reasonable.
 - (c) If the cost overrun is not approved, the holder shall submit a new application for CON, except that no letter of intent shall be required. Failure of the holder to submit such an application shall result in the Department applying applicable penalties under Section 71.04.
 - (d) Notwithstanding any of the previous subsections, no holder of a CON is entitled, without prior approval as specified herein, to spend in excess of the capital expenditure maximum. When the expenditure maximum is reached, the holder is required to cease incurring obligations for further expenditures until the Department has finally acted upon the proposed cost overrun.
- (5) **Periodic review.** After the issuance of a CON, the Department shall periodically review the progress of the holder in meeting the timetable for making the service or equipment available or for completing the project as specified in the approved application. A CON shall expire if the project for which it was issued is not commenced within 12 months following its issuance. The Department may grant an extension for an additional specified time not to exceed 12 months if good cause is shown why the project was not commenced. The Department may require evidence of the continuing feasibility and availability of financing for a project as a condition for extending the life of the certificate. In addition, if on the basis of its periodic review of progress under the certificate, the Department determines that the holder is not otherwise meeting the timetable and is not making a good faith effort to meet it, the Department may, after a hearing, withdraw the CON. The applicant shall issue to the department periodic reports as designated in the certificate of need approval notification on the impact of the service on the health status, quality of care and health outcomes of the population served and the characteristics of the payor mix for the population served. These reports may not be in less than 12-month intervals following the start of service approved in the CON.
 - (a) Requests for extension of a CON shall be made in writing to the Department no later than 30 days prior to the expiration of the original CON or extended period, whichever is applicable. The request shall state

the reason why the project could not be implemented during the original implementation period, what steps have been taken to assure that the project can be implemented during the extension period and the length of the extension necessary to complete the implementation. The initial extension period will be limited to no more than six months in duration.

- (b) If a CON and any extension expire prior to commencement of an approved project, a new CON application is required. No new letter of intent will be required.
- (c) In the event a holder of a CON is litigating a complaint relative to the issuance of said certificate, then the project shall be deemed to have commenced subject to the following.
- (d) Procedures for withdrawing a CON by the Department.
 - (i) If a holder of a certificate is not meeting the timetable for completion of the project and it appears to the Department that the holder may not be making a good faith effort to meet it, the holder shall show cause why the certificate should not be withdrawn.
 - (ii) The Department shall notify a holder in any case in which noncompliance with the timetable is suspected. The holder shall thereafter have 10 business days in which to file a detailed written response stating precisely how the project stands with respect to the timetable and, if the project may be behind schedule, stating with specificity all facts bearing on whether the holder is making a good faith effort to meet the timetable. All documents supporting the holder's response shall be appended to such response.
 - (iii) If, after reviewing the holder's response, it appears that the holder may not be in compliance, the Department may conduct a hearing to determine compliance. The hearing shall be conducted in accordance with Chapter 375, subchapter IV of the Maine Administrative Procedures Act. It shall be the burden of the holder in any such proceeding to demonstrate compliance with the timetable or good faith efforts to meet the timetable.
 - (iv) The Department may, if circumstances warrant, proceed directly to a hearing under subsection (iii) above without making the inquiry specified in subsection (ii).

(P) Departmental Reconsideration.

- (1) **Cause to be shown.** Any person directly affected by a review may, for good cause shown, request in writing a hearing for the purposes of reconsideration of the decision of the Department to issue or deny a CON. If good cause has been demonstrated, the Department shall hold a hearing to reconsider its decision. To be effective, a request for a hearing shall be received by the Department within 30 days of the Department's decision. If the Department determines that good cause

for a hearing has been demonstrated, the hearing shall commence within 30 days of receipt of the request. A decision shall be rendered within 60 days of the commencement of the hearing. The decision may be rendered beyond this time period by mutual consent of the parties. For purposes of this section, and in accordance with 22 M.R.S.A. Section 340, a request for a hearing shall be deemed to have shown good cause if it:

- (a) Presents significant, relevant information not previously considered by the Department which, with reasonable diligence, could not have been presented before the Department made its decision; or
 - (b) Demonstrates that there have been significant changes in factors or circumstances relied upon by the Department in reaching its decision; or
 - (c) Demonstrates that the Department has materially failed to follow its adopted procedures in reaching its decision; or
 - (d) Provides other bases for a hearing that the Department has determined constitutes good cause.
- (2) **Conduct of hearing.** The hearing shall be conducted in accordance with Chapter 375, subchapter IV of the Administrative Procedures Act. The scope of the hearing shall be limited to the issue(s) that the Department determines constitute good cause for the purpose of commencing the hearing. After the close of the hearing, the hearing officer shall promptly forward the hearing record to the commissioner for the commissioner's consideration in rendering a decision.
- (3) **Petition for reconsideration.** A person requesting a hearing for reconsideration must submit all material relevant to the determination of whether a hearing should be held, including any supporting documentation, in a single, all inclusive, petition within 30 days of the Department's decision. Material received after the receipt of the single petition will not be considered in determining whether to hold a hearing.

(Q) Judicial Review.

- (1) Any person aggrieved by a final decision of the Department made under the CON Act shall be entitled to a review in accordance with the Maine Administrative Procedures Act. A decision of the Department to issue a CON or to deny an application for a CON shall not be considered final until the Department has taken final action on a request for reconsideration on Section 71.05(P).
- (2) In judicial review involving competitive reviews of proposals to construct new nursing facility beds, the court shall require the party seeking judicial review to give security in such sums as the court determines proper, for the payment of costs and damages that may be incurred or suffered by any other party who is found to have been wrongfully delayed or restrained from proceeding to implement the CON, except that for good cause shown and recited in the order, the court may waive the giving of security. A surety upon a bond or undertaking under this

section submits the surety to the jurisdiction of the court and irrevocably appoints the clerk of the court as the agent for the surety upon whom any papers affecting liability on the bond or undertaking may be served. The liability of the surety may be enforced on motion without the necessity of an independent action. The motion and such notice of the motion as the court prescribes may be served on the clerk of the court who shall mail copies to the persons giving the security if their addresses are known.

(R) Implementation Reports.

- (1) Implementation reports required.** A summary report shall be made when the service or services for which the CON was issued becomes operational. Periodic reports shall be filed at the end of each 6-month period following the issuance of a CON regarding implementation activities, obligations incurred, and expenditures made. For a period of one year following the implementation of the service or services for which the CON was granted, the provider shall file, at 6-month intervals, reports concerning the costs and utilization. Report forms will be provided by the Department.
- (2) Final plans and specifications submission required.** Any holder of a CON which has been issued for the construction or modification of a facility or portion thereof shall file final plans and specifications therefore with the Department within 6 months, or any other time that the Department may allow, following the issuance of the certificate for review by the Department to determine that the plans and specifications are in compliance with applicable licensure, life safety code and accreditation standards.
- (3) Penalty.** The Department may revoke any CON it has issued when the person to whom it has been issued fails to file on a timely basis, reports, plans or specifications required by this section. The department shall review services that fall below the required volume and quality standards of a CON.

(S) Other Provisions.

- (1) Emergency Reviews.**

 - (a)** Upon the written or oral request of an applicant asserting that an emergency situation exists, the Department shall immediately determine whether an emergency situation exists and upon finding that an emergency situation does exist shall issue a CON for a project necessary on account of the emergency situation. The scope of the CON may not exceed that which is necessary to remedy or otherwise effectively address the emergency situation. The CON may be subject to conditions consistent with the purpose of this Act that do not interfere with the applicant's ability to respond effectively to the emergency.
 - (b)** The commissioner shall determine that an emergency situation exists whenever the commissioner finds that an applicant has demonstrated:

- (i) The necessity for immediate or temporary relief due to natural disaster, fire, unforeseen safety consideration, major accident, equipment failure, foreclosure, receivership or action by the Department or other circumstances determined appropriate by the Department;
 - (ii) The serious adverse effect of delay on the applicant and the community that would be occasioned by compliance with the regular requirements for CON; and
 - (iii) The lack of substantial change in the facility or services that existed before the emergency situation.
- (c) In an emergency situation the Department may waive in writing any penalties for failure to receive a CON for an otherwise reviewable project. After the emergency is resolved the Department will review the action to determine whether any additional review is required.
- (2) **Amended Applications.** An application may only be amended in the following circumstances: Any applicant may submit a revision to an application at any time prior to the date on which the preliminary report is submitted to the Commissioner of the Department. The Department may declare the revised application a new application and process it in accordance with the provisions of these rule pertaining to new applications. No letter of intent will be required. Persons directly affected by a review of the revised application will have access to the revised preliminary analysis and the rights to a public hearing under Section 71.05(G). The Department may limit the scope of the verbal or written testimony and/or evidence presented at the public hearing to information directly related to the portion of the application that has been revised.
- (3) **Voluntary withdrawal of application.** During the review period, prior to the date that staff submits a final report to the Commissioner, an applicant may withdraw an application without prejudice by filing written notice of the withdrawal with the Department. A withdrawn application may be resubmitted at a later date, as a new application requiring a new letter of intent, filing fees and review.
- (4) **Suspension of review.** Any applicant may request and be granted a suspension of the review process prior to the date on which staff submits its final analysis to the Commissioner. A request for suspension of the review process shall be for specific periods of no less than 60 days and not greater than one twelve month period in duration. Such a request, if granted, shall have no effect on competing applications which shall continue to be reviewed without interruption. Failure to reactivate within this time period will result in automatic withdrawal of the suspended application.
- (5) **Reapplication.** A period of three (3) years from the date of the Department's decision to deny a CON must lapse before an applicant denied a CON for a

proposed expenditure or action can reapply for a CON covering the same or significantly similar proposal, except whenever the Department determines that:

- (a) There has been a substantial change in existing or proposed facilities or services of the type proposed in the area served or proposed to be served by the applicant; or
 - (b) There has been a substantial change in the need for health facilities or services of the type proposed in the area served or proposed to be served by the applicant.
- (6) **Conflict of interest.** In addition to the limitations of Title 5, M.R.S.A., section 18, a member or employee of the Department who has a substantial economic or fiduciary interest which would be affected by a recommendation or decision to issue or deny a CON or who has a close relative or economic associate whose interest would be so affected shall be ineligible to participate in the review, recommendation or decision making process with respect to any application for which the conflict of interest exists.
- (7) **Division of project to evade cost limitation prohibited.** A health care facility or other party required to obtain a CON may not separate portions of a single project into components, including, but not limited to, site facility and equipment, to evade the cost limitations or other requirements of this Act.
- (8) **Rules.** The Department shall adopt any rules, standard, criteria, plans or procedures that may be necessary to carry out the provisions and purposes of the CON Act. The Department shall provide for public notice and hearing on all proposed rules, standards, criteria, plans, procedures or schedules pursuant to Title 5, M.R.S.A., chapter 375. Unless otherwise provided by the CON Act, rules adopted pursuant to the CON Act are routine technical rules as defined by Title 5, M.R.S.A., chapter 375, subchapter II-A.
- (9) **Consultation on new technologies and needs.** In connection with the development of policies and procedures to implement the CON Act, the commissioner may, from time to time, consult with persons with relevant skill and experience. This may be in regards to new medical technologies and the impact of those technologies on the health care delivery system in the State; unmet need for health care services in the State; and the quality of health care.
- (10) **Cost-of-living adjustment.** Every 2 years, beginning January 1, 2005, the Department shall review the monetary figures contained in the CON Act. The Department shall revise those figures to correspond to changes in the Consumer Price Index medical index by adopting rules setting the new figures.
- (11) **Federal Funding.** The Department is authorized to accept any federal funds to be used for the purposes of carrying out this chapter.
- (12) **Public Information.** The Department shall prepare and publish at least annually a report on its activities conducted pursuant to this Act. The annual report must include information on all CON's granted and denied. With regard to all

certificates granted on a conditional basis, the report must include a summary of information reported and any accompanying statements by the commissioner or Department staff submitted regarding the reports.